K014225

JAN 17 2002

MERETEK
The Breath Test Company

510(k) Summary

1. COMPANY NAME AND ADDRESS

1.1 Sponsor

Meretek Diagnostics, Inc.
618 Grassmere Park Rd., Suite 20
Nashville, TN 37211

1.2 Submission Contact

Denise E. Spellman
Director of Quality Systems & Regulatory Affairs

Telephone: 1-800-945-8252 ext. 208
Facsimile: 1-615-333-6202
Email: denises@Meretek.com

2. DEVICE NAME

2.1 Proprietary Name

BreathTek™ - UBiT® UBT *for H. pylori*

2.2 Common Name

Breath Test for Helicobacter pylori; UBT

3. CLASSIFICATION

3.1 Product Code: MSQ

3.2 Regulatory Class: Class I

Corporate Offices and Breath Test Center 618 Grassmere Park Drive Suite 20 Nashville, TN 37211 Phone 615-333-6336 FAX 615-333-6202
Breath Test Center and Research Laboratory Medical Towers Building 1709 Dryden Road Suite 1513 Houston, TX 77030 Phone 713-799-1282 FAX 713-799-8395

4. SUBSTANTIAL EQUIVALENCE COMPARISON

BreathTek™ UBT for *H. pylori*	BreathTek™ - UBiT® UBT for *H. pylori*
Summarized Specimen Collection Method: ♦ Patient inserts new straw within 0.5 inch of the bottom of first tube. Patient takes deep breath, pauses momentarily then blows gently through the straw into the bottom of the vertically positioned tube for about 3 to 5 seconds. Tube is slowly withdrawn off straw by health care practitioner as patient continues to blow. Practitioner caps tube quickly. A backup tube is prepared. ♦ Health care practitioner prepares Pranactin-Citric by dissolving it in Reconstitution Cup with 4 oz. of potable water. ♦ Patient drinks dissolved Pranactin-Citric with new straw and health care practitioner starts timer previously set to 15 minutes. ♦ After 15 minutes wait, patient inserts new straw within 0.5 inch of the bottom of second tube. Patient takes deep breath, pauses momentarily then blows gently through the straw into the bottom of the vertically positioned tube for about 3 to 5 seconds. Tube is slowly withdrawn off straw by health care practitioner as patient continues to blow. Practitioner caps tube quickly. A backup tube is prepared.	**Summarized Specimen Collection Method:** ♦ Patient blows into 300 cc breath bag until full (evident when fully expanded). ♦ Health care practitioner prepares Pranactin-Citric by dissolving it in Reconstitution Cup with 4 oz. of potable water. ♦ Patient drinks dissolved Pranactin-Citric with straw and health care practitioner starts timer previously set to 15 minutes. ♦ After 15-minute wait, patient blows into 300 cc breath bag until full (evident when fully expanded).

BreathTek™ UBT for *H. pylori*	BreathTek™ - UBiT® UBT for *H. pylori*
Specimen Collection Time (post-dose): 15 minutes	**Specimen Collection Time (post-dose):** 15 minutes
Non-Drug Component Summary: ♦ Reconstitution Cup ♦ Barcode Labels ♦ three (3) straws ♦ four (4) glass specimen tubes (similar to blood collection tubes) with screw-on caps ♦ Package Insert approved in NDA # 20-586/S-004.	**Non-Drug Component Summary:** ♦ Reconstitution Cup ♦ Barcode Labels ♦ one (1) straw ♦ two (2) 300 cc breath bags each fitted with a mouthpiece that contains a check valve. See section III for bag description. ♦ Package Insert approved in NDA # 20-586/S-004 with added information regarding use of the modified BreathTek-UBiT UBT kit.

5. **Discussion of Similarities and Differences**

The scientific basis underlying the BreathTek™ UBT and the BreathTek™ - UBiT® UBT kit is identical. Both kits contain a pouch of Pranactin-Citric drug product, a reconstitution cup, sample collection containers, sample identification labels and a package insert. The parts lists of the two kits differ for types of sample collection containers, the configuration of the barcode labels and the quantity of straws provided. The UBiT version of the kit directly collects breath samples into two 300cc breath bags each fitted with a mouthpiece containing a check valve and the original kit collects breath samples via a straw into glass test tubes. The glass test tubes must be quickly sealed with screw-on caps to contain the breath; the check valve incorporated in the breath bags eliminates this concern. The original kit contains a back-up set of sample collection tubes to compensate for the fragility of the tubes' glass structure. Use of barcode labels will be mandatory for the original kit and optional for the UBiT version.

The two kits will coexist on the market and share the same package insert. The package insert will be modified to include the UBiT version's component list and step-by-step procedure for collecting samples. The package insert will instruct

the health care provider to analyze the tube samples using a GIRMS spectrometer and the bag samples using an UBiT IR spectrophotometer. The BreathTek™ - UBiT® UBT kit will be advertised for use with the UBiT IR 300 System (510(k) # K013371). The BreathTek™ kit will be advertised for use with the ABCA-NT Gas Isotope Ratio Mass Spectrometer System and the ABCA Gas Isotope Ratio Mass Spectrometer System.

Equivalency of the breath bag and glass sample collection tube was proven in non-clinical testing. Human breath samples and simulated breath samples were placed on stability at controlled room temperature. Breath samples were proven stable for three (3) days and simulated breath samples were proven stable for seven (7) days.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 17 2002

Ms. Denise E. Spellman
Director of Quality Systems and Regulatory Affairs
Meretek Diagnostics, Inc.
618 Grassmere Park Drive, Suite 20
Nashville, TN 37211

Re: k014225
Trade/Device Name: BreathTek™ – UBiT® UBT for *H. pylori*
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: Class I
Product Code: MSQ
Dated: December 20, 2001
Received: December 26, 2001

Dear Ms. Spellman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014225

Device Name: BreathTek™ - UBiT® UBT for *H. pylori*

Indications For Use:
The BreathTek™ - UBiT® UBT for *H. pylori* collection kit is intended for use in the qualitative detection of urease associated with Helicobacter pylori in the human stomach and as an aid in the initial diagnosis and post-treatment monitoring of Helicobacter pylori infection in adult patients. The test may be used for monitoring treatment if used at least four weeks following completion of therapy.

For these purposes, the test utilizes the UBiT IR spectrophotometer for the measurement of the ratio of $^{13}CO_2$ to $^{12}CO_2$content in breath gas.

For administration by health care professionals. To be administered under a physician's supervision.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K014225

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)